

**REMARKS/ARGUMENTS**

Claims 1-28 are pending in this application.

In the Office Action of October 1, 2003, the Examiner has rejected Claims 1–28 of the above-referenced application for double patenting over Claims 1–28 of U.S. Patent No. 5,164,796 (the “796 Patent”). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner asserts that the pending claims are not patentably distinct from the claims of the 796 Patent because the invention of the 796 Patent selectively uses semi-permeable membranes or compositions which operatively filter the fluid sample and encompasses the instant invention as claimed. The Examiner further asserts that the presently claimed filter component is an obvious modification of the device claimed in the 796 Patent.

Applicants respectfully submit that the present claims are patentably distinct from the claims of the 796 Patent. The claims of the 796 Patent require the presence of a sterilizable indicator means in a sealable, sterilizable container. The indicator means or sensor as provided in the specification of the 796 Patent comprise a solid composition or membrane which the Examiner asserts filters fluid samples. See the 796 Patent at column 3, lines 52-55. However, neither the indicator means nor the composition or membrane filter fluids. The membrane or composition only permits the passage of gas molecules. See the 796 Patent at column 3, line 55 through column 4, line 2. The indicator means is only exposed to changes in pH or CO<sub>2</sub> and is not directly exposed to the growth medium in the

container. See *Id.* In fact, the 796 Patent, which is directed to an instrument for monitoring microbial growth in a specimen, does not teach or suggest filtering any fluids at all. Further, the purpose of the instrument of the 796 Patent is to monitor microbial growth in a specimen by detecting changes in the indicator means and it would go against this purpose to filter fluids since the fluid in the specimen is a growth medium that enhances the production of microbial metabolic products. See the 796 Patent at column 3, lines 43-46. The present invention, though, is directed to a filter device for collecting microorganisms from a volume of a specimen and requires a filter mounted in the device which can filter clinical specimens such as blood or other body fluids and non-clinical specimens such as food, juices, cosmetics, shampoos, pharmaceuticals or consumer products. See the specification at page 4, lines 1-5. Accordingly, the invention of the 796 Patent does not disclose, teach or suggest a filter for filtering fluids as required in Claims 1-28 of the present invention and in fact teaches away from these present claims. Therefore, the present Claims 1-28 are patentably distinct from the claims of the 796 Patent and this rejection should be withdrawn.

Also in the Office Action, the Examiner has rejected Claims 1-21 of the above-referenced application for double patenting over Claims 1-21 of U.S. Patent No. 5,094,955 (the "955 Patent"). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner asserts that Claims 1-21 are not patentably distinct from Claims 1-21 of the 955 Patent because the invention of the 955 Patent selectively uses semi-permeable membranes or compositions which operatively filter the fluid sample and

encompasses the instant invention as claimed. The Examiner further asserts that the presently claimed filter component is an obvious modification of the device claimed in the 955 Patent.

Applicants respectfully submit that the present Claims 1-21 are patentably distinct from the claims of the 955 Patent. The claims of the 796 Patent require the presence of a sensor means in a sealable specimen container. The sensor means as provided in Claim 1 and the specification of the 955 Patent comprises a solid composition or membrane which the Examiner asserts filters fluid samples. See the 796 Patent at column 3, lines 66-68 and column 17, lines 41-45. However, the solid composition or membrane does not filter fluids. The solid composition or membrane only permits the passage of gas molecules. See the 955 Patent at column 4, lines 1-11. In fact, the 955 Patent, which is directed to a device for continuously monitoring biological activity in a specimen, does not teach or suggest filtering any fluids at all. Further, the purpose of the device of the 955 Patent is to monitor biological activity in a specimen container by detecting changes in the sensor means and it would go against this purpose to filter fluids since the fluid in the specimen container is a growth medium that enhances the production of microbial metabolic products which are detected by the sensor. See the 955 Patent at column 3, lines 61-66. The present invention, though, is directed to a filter device for collecting microorganisms from a volume of a specimen and requires a filter mounted in the device which can filter clinical specimens such as blood or other body fluids and non-clinical specimens such as food, juices, cosmetics, shampoos, pharmaceuticals or consumer products. See the specification at page 4, lines 1-5. Accordingly, the invention of the 955 Patent does not disclose, teach or suggest a filter for filtering fluids as required by Claims 1-21 of the present invention and in fact teaches away

from these present claims. Therefore, the present Claims 1-21 are patentably distinct from the claims of the 955 Patent and this rejection should be withdrawn.

In addition, the Examiner has rejected Claims 22-28 for double patenting over Claims 1-9 of U.S. Patent No. 5,217,876 (the "876 Patent"). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner asserts that Claims 22-28 are not patentably distinct from Claims 1-9 of the 876 Patent because the invention of the 876 Patent selectively uses semi-permeable membranes or compositions which operatively filter the fluid sample and encompasses the instant invention as claimed. The Examiner further asserts that the presently claimed filter component is an obvious modification of the device claimed in the 876 Patent.

Applicants respectfully submit that the present Claims 22-28 are patentably distinct from the claims of the 876 Patent. The claims of the 876 Patent require the presence of a specimen container having a sensor means. The sensor as provided in the specification of the 876 Patent comprises a solid composition or membrane which the Examiner asserts filters fluid samples. See the 876 Patent at column 3, lines 52-55. However, the solid composition or membrane does not filter fluids. The solid composition or membrane only permits the passage of gas molecules. See the 876 Patent at column 3, lines 56-64. In fact, the 876 Patent, which is directed to a method for detecting microorganisms in a specimen, does not teach or suggest filtering any fluids at all. Further, the purpose of the method of the 876 Patent is to detect the presence of microorganisms in a specimen by monitoring changes in the indicator means of the sensor which result from gaseous products of an organism's

metabolic activity passing to the sensor means. It would go against this purpose to filter fluids from the specimen container since the fluid incubated with the specimen in the specimen container is a microbial growth medium that enhances the production of microbial metabolic products which are detected by the sensor. See the specification at column 3, lines 48-52. The present invention, though, is directed to a filter device for collecting microorganisms from a volume of a specimen and requires a filter mounted in the device which can filter clinical specimens such as blood or other body fluids and non-clinical specimens such as food, juices, cosmetics, shampoos, pharmaceuticals or consumer products. See the specification at page 4, lines 1-5. Accordingly, the invention of the 876 Patent does not disclose, teach or suggest a filter for filtering fluids as required by Claims 22-28 of the present invention and in fact teaches away from these present claims. Therefore, the present Claims 22-28 are patentably distinct from the claims of the 876 Patent and this rejection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the claims are in condition for allowance and prompt notice to that effect is earnestly solicited.

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Respectfully submitted,

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